

REMARKS

In the Office Action dated August 11, 2008, claims 1-13 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 1-13 of co-pending application Ser. No. 10/549,211. Claims 1-3, 8-11, 28, 29, 32 and 33 were rejected under 35 U.S.C. § 102(e) over U.S. Patent Publication No. 2002/0179166 to Houston et al. (Houston). Claims 12 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston. Claims 1-3, 8, 9, 12, 28-30, 32 and 33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over French Document FR 2 248 015 (FR '015).

In response to this rejection, applicants have filed herewith a Request for Continued Examination. Also, amendments to independent claims 1 and 3 were presented. Claims 1 and 3 have been limited to specify that the graft is "set" in a helical geometry. Support for the graft being "set" in the helical configuration can be found in the instant specification at page 16, line 20; page 19, lines 11-13; and page 28, lines 24-25. Applicants also submit herewith new claims 34-40. These include independent claim 37 and dependent claims 34-36 and 38-40.

Basis in dependent claims 34 and 38 for the graft being "thermally set" is found on page 14, line 23; page 16, line 35; and page 18, line 10. The recitation in claim 37 of the maximum helix angle being 35° is supported on page 6 at line 17 of the specification. The limitations in claim 35 and 39 that the tubing portion has a wall comprising a helical winding to help maintain a circular cross section finds support in the specification on page 26 at lines 9-20. The recitation in newly submitted claims 36 and 40 that the helix angle of the helical winding is greater than that of a helical center line finds support in the specification also. More particularly, the statement on page 26 at

lines 12-13 that the winding has "a large helix angle (close to 90°)." This should be compared to the maximum helix angle of the center line which is 35° or 45° (page 6, lines 12-34). This embodiment of the claimed invention is illustrated in Figure 9.

In the Office Action, the Examiner stated that applicant's arguments regarding Figure 5 of the Houston document were not persuasive, since Houston's Figure 5 "illustrates an embodiment wherein the mesh is longitudinally coiled and has a circular cross-section that induces a helical flow pattern upon a conduit within it." Applicants respectfully disagree.

First, it was stated in the Office Action that a tube with a line of sight along the inside is a limitation which is not in the pending claims. However, the graft recited in claims 1 and 3, as well as new claim 37, state that "the amplitude of the helical centerline is less than or equal to one half of the internal diameter of the tubing portion." Such a restricted geometry well nigh requires that a line of sight exists along the inside of the tubing portion. This is described in the instant specification on page 5, at lines 15-24. Moreover, Houston in Figure 1 shows an example of a graft with the geometry where the helical amplitude A is smaller than the internal diameter D and a line of sight is easily seen along the inside of the tube.

Second, Figure 5 of Houston discloses "a longitudinally coiled mesh structure [which] is conformed to induce upon a conduit within it a helical flow pattern" (see paragraph 51 of Houston). That is, Figure 5 of Houston discloses an external stent, rather than a graft as recited in the pending claims. Thus, the mesh structure of Figure 5 in Houston cannot define a flow lumen as the mesh material shown in Figure 5 of Houston is incapable of carrying fluid by itself.

Alternatively, if it is being argued in the Office Action that a conduit within the mesh structure of Houston's Figure 5 is considered to define the flow lumen, such structure fails to show a helical center line of the flow lumen having an amplitude less than or equal to one half of the internal diameter of the tubing portion which defines the flow lumen. In addition, a conduit within the mesh structure of Houston's Figure 5 would be even further away from the constrained geometry of the flow lumen which is recited in independent claims 1, 3 and 37 of the instant application. This is due to the wall thickness of the conduit itself. Put another way, any such conduit within the mesh of Houston's Figure 5 would be further away from the geometry of independent claims 1, 3 and 37, as the internal diameter of the conduit would be smaller than that of the mesh structure (due to wall thickness), while the helical amplitude of the conduit would remain the same as that of the mesh structure itself.

Third, it was argued in the Office Action "Houston's Figure 5 is simply an example of the shape of the device and if the helix angle is described by use and were to be illustrated with the desired helix angle disclosed in paragraph 62, the tubing would provide a line of sight along its inside." Applicants respectfully disagree. There is no discussion in Houston of the helical amplitude of the mesh illustrated in Figure 5. In fact, applicants could find no discussion of helical amplitudes anywhere in the Houston document. Therefore, even if the helix angles discussed in paragraph 62 are applied to the embodiment shown in Figure 5 of Houston, one does not achieve the geometry defined in applicants pending independent claims 1, 3 and 37, as the helical amplitude remains the same (there being no teaching in Houston to vary it). Thus, the ratio of the helical amplitude to the internal diameter would also remain the same in Houston. In sum, there is no disclosure in Houston of a geometry with a helical centerline which is

less than or equal to one half of the internal diameter of the tubing portion.

As a result, applicants respectfully submit that independent claims 1 and 3 are novel over Figure 5 of Houston, even without the amendments being submitted herewith. However, applicants have amended independent claims 1 and 3 and submitted independent claim 37 with an additional limitation, namely, that the graft is set [in a helical configuration]. By contrast, the conduit inserted within the mesh structure of Figure 5 of Houston is clearly not set in the shape which is imposed on it by the mesh structure. Otherwise, the mesh structure of Houston would be unnecessary and superfluous.

Moreover, Houston teach, in paragraph 51, that "a helical flow path can be induced within a conduit by means of the confirmation imposed by a structure along its longitudinal axis...in Figure 5; longitudinally coiled mesh structure 11 has a circular cross section throughout [and] is conformed to induce upon a conduit within it a helical flow pattern" (underlining added). Thus, Houston states that the conduit within the mesh structure shown in Figure 5 would be clearly initially cylindrical in shape and would then be induced by the mesh structure surrounding it to adopt a helical shape.

As a result, the feature of the graft being set in the helical configuration clearly defines over Houston. Moreover, there is no hint in Houston that the conduit described in relation to Figure 5 could be preset in a shape giving rise to a helical flow pattern. In fact, that would be counter to the explicit teaching of Houston that the external mesh scaffold is used to impose a new shape on a conventional, i.e., cylindrical, conduit. As a result, it is respectfully submitted that independent claims 1, 3 and 37 are patentable over the disclosure of Houston, as well as the remaining cited art.

In addition, applicants have submitted several new dependent claims which further patentably distinguish over Houston. More particularly, dependent claims 34 and 38 limit the graft to being "thermally set." Dependent claims 35 and 39 introduce a helical winding to help maintain a circular cross section. Finally, dependent claims 36 and 40 limit the helical winding to having a helix angle greater than that of the helical center line. Applicants note that none of these features are disclosed in Houston.

In sum, applicants respectfully submit that all of the pending claims are in patentable condition over Houston, whether it is taken alone or combination with other cited references.

Another reference employed in the Office Action was FR '015. It is stated in the Office Action that Figure 2 of this reference discloses a tube with a helix angle of approximately 55°. It was asserted in the Office Action that when the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. However, as applicants have noted before, FR '015 is concerned with anti-kinking properties of the tube. Therefore, this reference does not provide any reason to reduce the helix angle below that which is explicitly disclosed in FR '015.

It was asserted in the Office Action that "it would have been obvious to one of ordinary skill in the art at the time of the invention to decrease the helix angle as necessary for its intended use and desired outcome, while still providing an angle greater than zero to prevent kinking." It is recognized in the Office Action that the explicit teaching of FR '015 is devoted to anti-kinking. As a result, the explicit teaching of this reference gives no reason for reducing the helix angle. Only the instant claims recite a reduced helix angle. Only the instant specification explains the reasons for

reducing the helix angle. It is therefore respectfully submitted that it would not have been obvious to one of ordinary skill in the art at the time of the invention to decrease the helix angle shown in FR '015. This surely involves hindsight. Since the use of hindsight to go against the explicit teachings of FR '015 is not allowed, applicants respectfully submit that pending independent claims 1, 3 and 37 patentably define over FR '015, whether taken alone or in combination with other cited references.

Moreover, applicants submit that newly submitted independent claim 37, which recites a helix angle less than or equal to 35° patentably defines over FR '015. The limitation of the helix angle being less than or equal to 35° is well outside "the optimum or workable ranges" for the anti-kinking tubing which is disclosed in FR '015. Applicants respectfully submit that it would have required inventive skill to venture from the disclosed helix angle of 55° in FR '015 to formulate a maximum helix angle of 35°, as is now recited in independent claim 37.

As to the double patenting rejection maintained in the instant Office Action, applicants note that claims 1-13 were only provisionally rejected over claims 1-13 of co-pending application Serial No. 10/549,211. As the conflicting claims have not in fact been patented, applicants see no need to further address this issue at the present time.

In view of the foregoing, it is respectfully submitted that the pending claims are in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

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